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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,746	10/08/2003	Thomas J.F. Nieland	MIT 9952	8136

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PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE
SUITE 1200
ATLANTA, GA 30361

EXAMINER	
BALASUBRAMANIAN, VENKATARAMAN	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/681,746	Applicant(s) NIELAND ET AL.	
	Examiner Venkataraman Balasubramanian	Art Unit 1624	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *08 June 2006*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See attached Advisory Action*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-17*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: See attached Advisory Action.

Venkataraman Balasubramanian

Venkataraman Balasubramanian
Primary Examiner
Art Unit: 1624

6/16/06

ADVISORY ACTION

The applicants' response, which included amendment to claims 5 and 10, filed 6/08/2006 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered for the following reasons.

Claims 1-17 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim and share the same limitation

1. Recitation of "Table 1",. in amended claim 1 renders claim 1 and its dependent claims indefinite as it is not clear what Table 1 is being referred to. whether the claim is compound claim or composition claim or a method of use claim. Claim 1 is indefinite as it refers to a Table of compounds which is not in the claims but in the disclosure. See MPEP 2173.05(s), which states:

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more

concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

The same applies to claim 4, which also refers to Table 1.

This rejection is same as made in the previous office action and is maintained. Applicants are urging one to read the limitations of the specification into these claims, which is not proper.

Applicants may incorporate Table 1 in these claims to obviate this rejection. However, as noted in the previous office action several issues related to the structures should be clearly addressed. These include structures having nitrogen and or oxygen with open valence, salt lacking a negative charge and some structures are clearly not discernable as to what they are which would result in printer query. See entire Table. For mention a few, see MIT9952-25, 30, 37, 39, 40, 41, 44, 63, 64, 66, 68, 75, 137, 146, 152, 158, 159, 178, 197, 251, 275, 299, 300, 301, 36, 307, 308, 316, 317, 321 and 342. In short, the entire Table need to be revised for clear depiction of the structures. In addition, the Table also has several structures, which are duplicates. See 3, 7, 81 or 16, 83, or 2,80, or 14, 86.

2. Claim 2 is a duplicate of claim 1 as there is no material difference between claim 1 and claim 2. Note both have same scope as they rely on same pharmaceutical composition. Note intended use is not given any weight in such a pharmaceutical composition. Note In re Tuominen 213 USPQ 89. Also See Intirtool, LTD. V. Texar

Corp., 70 USPQ2D 1780. Note court held that " In general, a claim preamble is limiting if recites essential structure or steps or if it is necessary to give" life, meaning, and vitality to claim.'.... However, if the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not effect the structure or steps of the claimed invention,' the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art.""

Instant claim is a composition claim of compound and the compound is clearly defined by a structure shown in Table 1. Omission of the attributes to the composition of the compounds of Table 1 would not alter the structure of these compounds and hence the composition. Although claim 2 depends on claim 1 and would share the functional limitation recited in claim1, a compound is a compound irrespective of is functional property.

Applicants' argument to overcome this rejection is not persuasive for reasons of record and stated above. As for dosage issue, Claim 1 would include some amount of the active ingredient and therefore would have dosage of the said compound. There is no material difference. A pharmaceutical composition is a pharmaceutical composition irrespective of the intended use. Hence, this rejection is proper and is maintained.

3. Claim 5 is an improper depended claim as it depends on claim 4 for method of use and claim1 for pharmaceutical composition of active ingredient.

If the amendment were entered, this rejection would be deemed as obviated.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' amendment to the Table 1 in specification and the suggestion they may incorporate the Table In claim 1 and 4 has resulted in the introduction of new matter. Both the specification and the provisional application have no recitation of the specific species and it is not clear where the support for the modification of the structures of the compounds of Table 1 comes from. One is asked to guess that applicants' amendment as proper without any support.

Contrary to applicants' urging, the changes are not typographical errors. They are structural changes.

Since, these are vendors compounds there should be a document to show these changes are proper and meet the legal standard for not introducing new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected 35 U.S.C 102(b) as being anticipated by ChemBridge DiverSet.

As acknowledged by the applicants the compounds of the Table 1 is from ChemBridge DiverSet and hence are known and available to public as evident from the Brochure provided by the applicants.

The Brochure clearly identifies the compound set as drugs and hence a pharmaceutical composition derived from them is clearly anticipated.

It is clear that these compounds are known compounds.

See also In re Best 195 USPQ 430. Particularly note In re Best has the following quote " Where Patent Office has reason to believe that functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may, in fact, be an inherent characteristic in the prior art, it possesses the authority to require applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on". See MPEP 2112.

This rejection is same as made in the previous office action. Since the instant claim is not a method of use claim, this rejection is proper.

Applicants' argument that instant compounds are drug while the vendors are drug-like compounds is not persuasive. First of all, applicants are merely using the vendors' compounds to screen. Thus, whatever attributes applicants assert for their compounds would be present in vendors' compounds. Secondly, applicants have not defined what is "drug" and what is "drug-like compound". The compounds are form a diversity library for screening and therefore can be incorporated pharmaceutical

composition. The fact the diversity library is large does not make any difference. A compound is a compound and it can be incorporated into a composition.

Hence, this rejection is proper.

Claims 10-17 are rejected 35 U.S.C 102(b) as being anticipated by Krieger et al., US2002/0099040.

Krieger et al., teaches several SR-B1 antagonists and their use, which include generically claimed instant compound and the method of use.

See entire document. Especially see pages 2-10, paragraphs 0012 to 0112 for details of the SR-B1, HDL, cholesterol transport, compounds that interact with SR-B1 or alter is expression, inhibition of uptake, binding or transport to SR-B1, screening assay, Northern analysis as well as pages 10-16 for examples 1-6. Note teachings of Krieger in these pages meet all the limitations claimed in claims 10-17.

Applicants' argument to overcome this rejection is not persuasive. First of all Krieger et al., has earlier priority date and even if the compounds of instant specification were included same as the provisional application, the instant claims does not include any compounds. It is generic screening assay and the target SR-B1 is known.

Hence this rejection as applied to screening is maintained.

Claims 10-17 are rejected 35 U.S.C 102(b) as being anticipated by Acton US 5.965,790

Acton teaches several compounds that alter SR-B1 expression, its role in lipid transfer, cholesterol transport along with screening assays for discovering drugs that regulate the expression of Sr-B1. See entire document. Especially see column 1-14 for

details of SR-B1 and its role n lipid and cholesterol transport. Particularly see column 9-10 for small molecules that interact with the gene and regulate Sr-B1 expression as well as column 12-31 for various assays for screening and evaluating such compounds. See claims 18-24 for the same. Note all the compounds taught by Acton are also generically claimed in the instant claims 1 and all the limitations recited in claims 10-17 are also taught by Acton.

Contrary to applicants' urging Acton et al. is a valid prior art. In addition, as recited, the instant claims do not include any compounds. Furthermore, Action in column 26-28 clearly teaches screening assays and high-thorough screening which are also recited in the instant specification. Morevover, contrary to applicants' urging that Acton et al relates to nucleic acid, the teachings include SR-B1 protein and its action.

Hence, this rejection is proper and is maintained.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

Venkataraman Balasubramanian

6/16/2006